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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/672,876

09/25/2003

Stephen Donovan

17607 (BOT)

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07/19/2006

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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,876

Applicant(s)

DONOVAN, STEPHEN

Examiner

Chih-Min Kam

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5 and 13-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,13-15,17-19 and 21 is/are rejected.
- 7) ☒ Claim(s) 16 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1, 5 and 13-21 are pending.

Applicants' amendment and response filed May 11, 2006 is acknowledged. Applicants' response has been fully considered. Claims 1, 13, 17 and 21 have been amended, and claim 4 has been cancelled. Therefore, claims 1, 5 and 13-21 are examined.

2. The status of claim 15 is indicated as "new", which is not correct. Appropriate correction is required.

Withdrawn Claim Rejection- 35 USC § 112

3. The previous rejection of claims 1, 4, 5 and 13-21 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claim, applicant's cancellation of the claim, and applicant's response at page 3 of the amendment filed May 11, 2006.

Maintained Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 5, 13-15, 17-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Lewis *et al.* (Production of Botulinum Toxin Vol. 53, pages 213-230 (1947)).

Lewis *et al.* disclose a culture media containing basal medium having Difco yeast extract 0.5 %, glucose (cerelease) 0.6 %, thioglycolic acid 0.05%, and tap water, adjusted to pH 7.5, and

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supplements including 0.1% of Peptecase (a tryptic digest of casein) and 2.5% of Gluten (granular product from corn) are used to produce botulinum toxin A having toxicity 10,000 MLD (Table 1, last line; pages 213-216; claims 1, 5, 14, 15 and 17), and the reference also indicates the recommended media can be Formula I containing 2% of milk (20 g powdered milk in one liter) or Formula II containing 0.3% of casein (3 g in one liter; which contains less than 1% animal product), glucose and corn steep liquor in water, where these formulas can be used to produce 500,000 to 1,000,000 MLD of toxin (page 228; claims 13, 18, 19 and 21). Although the reference does not specifically indicate the toxin was isolated, and the culturing is performed until cell density of the fermentation medium decreases due to cell lysis, the reference discloses the toxicity test which indicates the botulinum toxin was produced in the culture medium, and the culture media was incubated at 34 °C for three days (see footnote of Table 1), and the clostridium botulinum is incubated in the seed medium for 1-4 days at stage two of fermentation, and the growth in stage two seed medium proceeds for 3 days, as evidenced by Donovan (US 20050069562, paragraph [0076]). Thus, at the time of invention was made, it would have been obvious to one of ordinary skill in the art that botulinum toxin can be obtained from culturing the fermentation medium containing gluten and peptecase or casein (i.e., having less than 1% animal product) and the culturing is performed until cell density of the fermentation medium decreases (i.e., incubating for the same period as the claimed method), which results in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Response to Arguments

Applicants indicate Lewis does not disclose use of an animal product free method or composition, but is instead concerned with reducing or removing meat from the medium use to

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culture a *Clostridium botulinum* (see page 213), and Lewis uses animal proteins in all his processes (see page 214). Additionally, all of Tables 1-7 in Lewis disclose use of an animal protein to culture or to ferment an animal protein, where casein and Peptidase are milk proteins and are therefore clearly animal proteins (See page 21, lines 29 to page 22 line 2; and page 26, lines 14-15 of the specification of the instant patent application). Therefore, the rejection should be withdrawn (page 4 of the response).

Applicants' response has been fully considered, however, the arguments are not persuasive because the claim does not recite the fermentation medium is free of animal product in the claimed method, instead it recites the fermentation medium comprises no more than about one percent of animal product, and Lewis teaches the culturing medium for producing botulinum toxin type A contains less than 1% animal protein (e.g., casein or peptidase), which meets the criteria of the fermentation medium in the claimed method. Thus, the rejection is maintained.

Claim Objections

6. Claims 16 and 20 are objected to because the claim is dependent from a rejected claim, claim 1 or 13.

Conclusion

7. Claims 1, 5, 13-15, 17-19 and 21 are rejected; and claims 16 and 20 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



primary **CHIH-MIN KAM**
PATENT EXAMINER

CMK

July 14, 2006